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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,214	12/03/2003	Wendelin Samstag	1/1441	8889
28501	7590	11/03/2006	EXAMINER	
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			ANDERSON, REBECCA L	
		ART UNIT	PAPER NUMBER	
		1626		
DATE MAILED: 11/03/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/727,214	SAMSTAG ET AL.
	Examiner	Art Unit
	Rebecca L. Anderson	1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address.--

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 August 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-5 are currently pending in the instant application. Claims 1-5 are rejected.

Response to Amendment

Applicant's amendment and arguments filed 29 August 2006 have been considered and entered into the application. Applicants' amendment has overcome the objection to the specification; overcome the claim objections; and has overcome the 35 USC 112 1st and 2nd paragraph rejections of the claims. The 35 USC 102(b) and 35 USC 103(a) rejections are maintained. Applicants' argue that the limitations of the XRPD data of the 10 strongest peaks have been entered into the claims and that in comparison to the prior art the instant process crystallizes the product from an alcohol, ethanol, and not with water and ethanol. These arguments have been fully considered but they are not persuasive. Specifically, in regards to the XRPD data, the prior art is silent to this data, however, the prior art does put the specific crystalline product in the public domain. As the prior art references differ from the claims in that the references are silent on the crystalline form, applicant must show that their crystalline form really is different from any of the ones prepared in the prior art. MPEP 2112 states: "Something which is old does not become patentable upon the discovery of a new property. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." In this case, the "unknown property" is the particular crystalline form. This is unknown because the references are silent on this

property. MPEP 2112 goes on to state: "A rejection under 35 USC 102/103 can be made when the prior art product seems to be identical except that the prior art is silent as to an inherent characteristic. Again, the "characteristic" which the prior art is silent on is the crystalline form. This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also Ex parte Anderson, 21 USPQ 2nd 1241 and 1251, discussion of Rejection E. There, the decision states, "There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture." (page 1253). The "properties" branch of that statement applies here. Applicants are reminded that the PTO has no testing facilities. In regards to the argument about the prior art requirement of water and ethanol to prepare the crystal, it is noted that applicants' instant claims are drawn to process "comprising". The term "comprising" is considered open-ended language and therefore the process as claimed can include the use of water in the crystallization process. Additionally, applicant is directed to the instant claim 4 wherein water is added before crystallization is complete. Therefore the 35 USC 102 and 103 rejections are maintained.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,319,921. US Patent No. 6,319,921 discloses the process for preparing the

compound 8, column 49, which corresponds to the compound prepared by applicants' instant process. Column 49 states that the product LXXXIX, was reacted with LXVII from example 1 according to method B to provide 8. Referring back to example 1, method B, LXVII is reacted and the solid is recrystallized with water and ethanol.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,319,921.

Determining the scope and contents of the prior art

US Patent No. 6,319,921 discloses the process for preparing the compound 8, column 49, which corresponds to the compound prepared by applicants' instant process. Column 49 states that the product LXXXIX, was reacted with LXVII from example 1 according to method B to provide 8. Referring back to example 1, method B, LXVII is reacted and the solid is recrystallized with water and ethanol.

Ascertaining the differences between the prior art and the claims at issue.

The difference between the prior art and the claims at issue is that the prior art does not specify the amount of ethanol or the temperature of the reaction. Also, the XRD pattern of the instant claims, is not described in the prior art reference. However, the prior art reference does prepare a crystalline form of the same chemical substance.

Furthermore, The difference between the prior art and the instant claims 1 and 4 is that the X-ray diffraction pattern the crystalline solid of the prior art may differ from that of the X-ray diffraction pattern of the instant claims "polymorph". However, Brittain taught that "in the strictest sense, polymorphs are different crystalline forms of the same pure substance in which the molecules have different arrangements and/or different conformations of the molecules (see Brittain p. 1-2).

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art to prepare the claimed polymorph of 1-[tert-butyl-1-p-toyl-

1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphalen-1-yl]-urea by crystallizing in ethanol with a specific temperature or weight of ethanol as the Courts have decided per *In re Boesch*, 205 USPQ 215 (1980), that the optimization of variables, such as pH and molar ratios, in a known process is *prima facie* obvious. Therefore, the claimed process would have been suggested to one skilled in the art. Furthermore, mere difference in physical property is well known conventional variation for the same pure substance (see Brittain p. 1-2), i.e. *prima facie* obvious.

Claims 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,319,921 and WO 01/04115.

Determining the scope and contents of the prior art

US Patent No. 6,319,921 discloses the process for preparing the compound 8, column 49, which corresponds to the compound prepared by applicants' instant process. Column 49 states that the product LXXXIX, was reacted with LXVII from example 1 according to method B to provide 8. Referring back to example 1, method B, LXVII is reacted and the solid is recrystallized with water and ethanol.

WO 01/04115 discloses the process of preparing the compound of the formula (I) on page 18, by reacting 4-amin-1-(2-morpholinethoxy)naphthalene with 5-(2,2,2-trichloroethoxycarbonyl)amino-2-tert-butyl-1-p-tolylpyrazole in the presence of a secondary amine and a solvent consisting of DMSO and ethyl acetate, see pages 19 and 20.

Ascertaining the differences between the prior art and the claims at issue.

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The difference between the prior art and the claims at issue is that the prior art does not specify the specific molar ratios as claimed. Also, the XRD^P of claim 5, is not described in the prior art reference. However, the prior art reference does prepare a crystalline form of the same chemical substance.

Furthermore, The difference between the prior art and the instant claims is that the X-ray diffraction pattern the crystalline solid of the prior art may differ from that of the X-ray diffraction pattern of the instant claims. Brittain taught that "in the strictest sense, polymorphs are different crystalline forms of the same pure substance in which the molecules have different arrangements and/or different conformations of the molecules (see Brittain p. 1-2).

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art to prepare the claimed polymorph of 1-[tert-butyl-1-p-toyl-1H-pyrazol-5-yl]-3-[4-(2-morpholin-4-yl-ethoxy)naphalen-1-yl]-urea by crystallizing in ethanol with a molar ratio of the compounds found in WO 01/04115 as the Courts have decided per *In re Boesch*, 205 USPQ 215 (1980), that the optimization of variables, such as pH and molar ratios, in a known process is *prima facie* obvious. Therefore, the claimed process would have been suggested to one skilled in the art. Furthermore, mere difference in physical property is well known conventional variation for the same pure substance (see Brittain p. 1-2), i.e. *prima facie* obvious.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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October 31, 2006